

APPLICATION  
FOR  
UNITED STATES LETTERS PATENT

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PATENT APPLICATION

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SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that Gregory E. Sancioff of 120 Mill Road, North Hampton, NH 03862, Jack Robertson of 880 South Meriden Road, Cheshire, CT 06410 and Frederic P. Field of 5 Woodland Road, North Hampton, NH 03862 have invented certain improvements in CONNECTOR ASSEMBLY FOR JOINING A GRAFT VESSEL TO A SIDE OF A TARGET VESSEL, of which the following description is a specification.

KK/ONUX35.CVR

CONNECTOR ASSEMBLY FOR JOINING A GRAFT  
VESSEL TO A SIDE OF A TARGET VESSEL

CROSS-REFERENCE TO RELATED APPLICATIONS

5           This patent application claims benefit of:

          (1) pending prior U.S. Provisional Patent  
Application Serial No. 60/412,592, filed September 20,  
2002 by Gregory E. Sancoff et al. for A CONNECTOR  
ASSEMBLY FOR JOINING A GRAFT VESSEL TO A SIDE OF A  
10 TARGET VESSEL (Attorney's Docket No. ONUX-35 PROV); and

          (2) U.S. Provisional Patent Application Serial  
No. 60/455,363, filed March 17, 2003 by  
Gregory E. Sancoff et al. for A CONNECTOR ASSEMBLY FOR  
JOINING A GRAFT VESSEL TO A SIDE OF A TARGET VESSEL  
15 (Attorney's Docket No. ONUX-35 A PROV).

          The two above-identified patent applications are  
hereby incorporated herein by reference.

Field Of The Invention

20           This invention generally relates to apparatus and  
methods for surgery. More specifically, this invention  
relates to apparatus and methods for the surgical

ONUX-35

anastomosis of physiological vessels, and particularly for joining a graft vessel to a target vessel.

#### Background Of The Invention

5           It is a common surgical procedure to join together two or more surgical vessels, such as intestines or blood vessels. The three main types of connections include: end-to-end, end-to-side, and side-to-side connections. As these structures often carry fluid,  
10           the connections formed must generally be at least substantially complete around the entire surface of the joiner. Traditional means for connecting together these structures include the use of sutures or staples.

          Placing sutures by hand around the circumference  
15           of a vessel is often very difficult and cumbersome due to various factors. These factors include space limitations at the typical surgical site (e.g., at an interior surgical site); limited angles of approach to the surgical site; and the nature of the attachment of  
20           the desired surgical vessel to, or containment within, various other structures. Such limitations typically cause difficulty in accessing remote sides of the

desired anatomical vessels and impede the manipulation of surgical instruments at the surgical site.

5        Additionally, blood vessels such as the coronary arteries, or those vessels used to form bypasses, are typically fairly small in diameter and have very thin walls. The thin walls frequently cause these vessels to adopt a collapsed configuration during handling, which in turn causes difficulty in handling and positioning the vessels.

10        Accordingly, there is a need for an improved apparatus and method for joining a graft vessel to an opening in a target vessel.

#### Summary Of The Invention

15        An object of the present invention is, therefore, to provide an apparatus for joining a graft vessel to a target vessel and to provide a method for joining a graft vessel to a target vessel.

20        With the above and other objects in view, a feature of the present invention is the provision of a connector assembly for joining a graft vessel to an opening in a target vessel. The connector assembly

comprises a tubular connector member provided with a plurality of tines at a distal end thereof, the tines in an unstressed state extending inwardly toward a central axis of the tubular connector member and then substantially radially outwardly from the central axis of the tubular connector member and then proximally at sharp ends thereof, the tines being adapted to engage end portions of the graft vessel and thereafter wall portions of the target vessel; and a spreader portion comprising a tubular body slidably disposed in the tubular connector member and movable in the tubular connector member so as to engage the inwardly extending tines and force the tines of the tubular connector member into positions substantially disposed in a hypothetical extension of walls of the tubular connector member. A seal portion is slidably disposed around the tubular connector member and is provided with flanges at a distal end thereof for engagement with the target vessel in wall areas proximate the tines to clamp the target vessel wall portions to the tines.

In accordance with a further feature of the invention, there is provided a method for joining a graft vessel to a target vessel. The method includes the steps of providing a connector assembly having  
5 graft supporting structure at a distal end thereof for supporting an everted end of the graft vessel and pressure exerting structure at another portion thereof for exerting distally directed pressure on the graft vessel everted end, providing a deployer assembly for  
10 holding, manipulating, and releasing the connector assembly, attaching the connector assembly to the deployer assembly, extending the graft vessel through the deployer assembly and the connector assembly, with a distal end of the graft vessel extending distally of  
15 the distal end of the connector assembly, everting the distal end of the graft vessel back upon the connector assembly graft supporting structure, producing an opening in the target vessel if one is not already available, manipulating the deployer assembly to move  
20 the everted end of the graft vessel through the target vessel opening, into the target vessel, and into

engagement with an interior wall of the target vessel  
around the opening therein,  
manipulating the deployer assembly to move the  
connector assembly pressure exerting structure into  
5 engagement with an exterior wall of the target vessel  
proximate the everted end of the graft vessel, and  
disconnecting the deployer assembly from the connector  
assembly, whereby to hold the everted end of the graft  
vessel and an area of the target vessel adjacent the  
10 graft vessel between the connector assembly pressure  
exerting structure and the connector assembly graft  
supporting structure.

The above and other features of the invention,  
including various novel details of construction and  
15 combinations of parts and method steps, will now be  
more particularly described with reference to the  
accompanying drawings. It will be understood that the  
particular device and method embodying the invention  
are shown by way of illustration only and not as  
20 limitations of the invention. The principles and  
features of this invention may be employed in various

and numerous embodiments without departing from the scope of the invention.

Brief Description Of The Drawings

5           Reference is made to the accompanying drawings in which are shown illustrative embodiments of the invention, from which its novel features and advantages will be apparent.

          In the drawings:

10           Fig. 1 is an exploded perspective view of one form of connector assembly illustrative of an embodiment of the invention;

          Fig. 2 is a perspective view of the connector assembly of Fig. 1, showing the components of the  
15           assembly telescopically joined together;

          Fig. 3 is a view similar to that of Fig. 2, but shows the connector assembly components further joined telescopically;

          Fig. 4 is a perspective view of a deployer  
20           assembly and the connector assembly, shown separately;



Fig. 5 is a perspective view of the deployer assembly of Fig. 4, with the components thereof assembled;

Figs. 6-8 illustrate mounting of the connector assembly on the deployer assembly;

Figs. 9-14 diagrammatically illustrate steps in a method for joining a graft vessel to a target vessel, using the connector and deployer assemblies of Figs. 1-5, and illustrative of an embodiment of the invention;

Fig. 15 is similar to Fig. 1, but illustrating an alternative embodiment of connector assembly components; and

Figs. 16-18 diagrammatically illustrate steps in a method for joining a graft vessel to a target vessel, using an end-to-end fixation.

#### Detailed Description Of The Preferred Embodiments

Referring to Fig. 1, it will be seen that a connector assembly 20 includes a tubular connector member 22, a spreader portion 24, and a seal portion 26.

The tubular connector member 22 is provided with a tubular body portion 28 and a plurality of tines 30 extending distally from a distal end 32 of the body portion 28. The tines 30 each include a leg portion 34 extending inwardly toward a central axis a-a of the tubular connector member 22, a flange portion 36 extending substantially radially outwardly from the central axis a-a of the tubular connector member 22, and a sharp end portion 38 extending proximally from an outer extremity of the flange portion 36. As will be further described herein below, the sharp end portions 38 of the tines are adapted to penetratingly engage an end portion of a graft vessel G (Fig. 10) and, thereafter, wall portions of a target vessel T (Fig. 13). The tubular connector member 22 is further provided with opposed radially outwardly extending flanges 40 (Fig. 1) at a proximal end 42 of the tubular connector member 22.

The spreader portion 24 includes a tubular body 44 which is adapted for sliding disposition in the tubular connector member 22. The spreader portion 24 is telescopically movable in the tubular connector member

22 so as to engage the inwardly extending tines 30 and  
force the tines 30 into positions substantially  
disposed in a hypothetical extension of the tubular  
body portion 28 of tubular connector member 22. The  
5 spreader portion 24 is provided with opposed outwardly  
extending flanges 46.

The seal portion 26 is adapted for sliding  
disposition around the tubular connector member 22 and  
the spreader portion 24. The seal portion 26 includes  
10 a tubular body 48 provided, at its distal end 50, with  
a ring of flanges 52 extending radially outwardly, and  
at its proximal end 54 with opposed outwardly extending  
flanges 56. The tubular body 48 of seal portion 26 is  
further provided with opposed slots 58 extending  
15 distally from the proximate end 54 of the tubular body  
48.

Referring now to Fig. 2, it will be seen that the  
spreader portion 24 is disposed within the tubular  
connector member 22. In Fig. 2, the spreader portion  
20 24 is shown sufficiently advanced in the tubular  
connector member 22 to force the tines 30 into the  
aforesaid positions disposed in a hypothetical

extension of the tubular body portion 28 of tubular connector member 22.

In Fig. 3 there is shown the same assembly as is shown in Fig. 2, but with the seal portion 26 advanced distally so as to position the flanges 52 of the seal portion 26 proximate the flange portions 36, and sharp end portions 38, of the tubular connector member 22.

In Fig. 4 there are shown components of a deployer assembly 60, including a grabber 62, a holder 64, and a pusher 66. The grabber 62 is provided with a widthwise slot 68 for receiving a pin 70. The holder 64 is provided with an aperture 72 therethrough which is alignable with the grabber slot 68 and configured to receive the pin 70. The pusher 66 is provided with a lengthwise slot 74 for receiving the pin 70. Thus, the grabber 62, holder 64, and pusher 66 are connected together (Fig. 5) by the pin 70 which, in combination with the slots 68, 74, permits limited rotative movement of the grabber 62 and limited axial movement of the pusher 66.

As shown in Fig. 6, the holder 64 is provided with slots 76 adapted to receive the flanges 40 of tubular

connector member 22 when the connector assembly 20 is  
inserted in the distal end of the deployer assembly 60  
(Fig. 7). The grabber 62 is provided with widthwise  
extending lugs 78 which, upon rotation of the grabber  
5 62 (Fig. 8), slide under the flanges 40 of tubular  
connector member 22 so as to hold the tubular connector  
member 22 in the deployer assembly 60.

Figs. 9-14 illustrate one preferred manner for  
using connector assembly 20 to join the end of a graft  
10 vessel G to the side of a target vessel T.

Referring next to Fig. 9, it will be seen that in  
a preferred use of the connector assembly 20 in  
conjunction with the deployer assembly 60, pusher 66 is  
advanced distally (Fig. 9A) which causes spreader  
15 portion 24 to advance distally, whereby to spread the  
tines 30 apart and thereby facilitate loading a graft  
vessel onto connector assembly 20. More particularly,  
with the tines 30 opened up, the graft vessel G (Fig.  
9A) is fed into the deployer assembly 60 by way of  
20 openings 80, 82 in sides of the grabber 62 and holder  
64, respectively. The graft vessel G is further  
extended through a concavity 85 in the pusher 66 and

through the connector assembly 20 (with its opened-up  
tines 30) and slightly beyond. Once this has been  
done, pusher 66 is withdrawn proximally (Fig. 9B) so as  
to permit tines 30 to return inwardly again, whereby to  
5 facilitate eversion of the graft vessel G over the tine  
sharp end portions 38.

More particularly, as shown in Fig. 10, the graft  
vessel G is everted back over the tine sharp end  
portions 38 and perforated thereby. Significantly,  
10 eversion can be effected with reduced trauma to the  
graft vessel G since the retraction of pusher 66  
permits tines 30 to return to their inboard position,  
thus causing less stress on the graft vessel during  
eversion. Also significantly, during eversion and  
15 thereafter, the flange portions 36 (Fig. 2) of tines 30  
help support and carry the everted graft tissue,  
including preventing the vessel from sliding radially  
inwardly and/or upwardly along the tines, which could  
affect the integrity of the vessel joinder and/or  
20 expose the connector to blood flow.

A slot S (Fig. 11) is then cut in a wall of target  
vessel T and the tines 30 of the connector member 22

are inserted through the slot S and into the target vessel.

The pusher 66 is then pushed toward the target vessel T, which causes the spreader portion 24 to engage the connector member tines 30 to spread the tines radially outwardly (Fig. 12). The deployer assembly 60 is then pulled proximally slightly to cause the tine sharp end portions 38 to engage the target vessel T.

The pusher 66 is then again pushed distally (Fig. 13), causing distal movement of the seal portion 26 to bring the seal portion flanges 52 into engagement with the target vessel T proximate the tine flange portions 36 and sharp end portions 38 (Figs. 13 and 14). At this point, tabs 84 (Fig. 1) on the spreader portion 24, and tabs 86 on the seal portion 26, snap into slots 88 in the connector member 22. The tabs 84 and 86 are bent slightly outwardly and inwardly, respectively, to engage the slots 88. The tabs 84, 86 can interface with a multitude of slots 88 to provide a selection of gaps between the tine flange portions 36

and the seal portion flanges 52, to accommodate different thicknesses of tissue.

Upon completion of the vessel joining operation, the grabber 62 is rotated to release the connector assembly 20 and the pusher 66 is pushed distally to  
5 eject the connector assembly 20 from the deployer assembly 60.

Significantly, due to the manner in which connector assembly 20 engages graft vessel G and target  
10 vessel T, there is substantially no contact between the connector assembly and blood flowing in graft vessel G and/or blood flowing in target vessel T, thus minimizing stenosis or other lumen occlusion, blood leakage, infection, adverse tissue reactions, blood  
15 flow turbulence, blood clotting and the like.

In some instances, as when working with particularly delicate vessels, the connector member 22 may be provided without the sharp end portions, as shown in Fig. 15. In this case, the connector assembly  
20 effects the connection between the two vessels G, T by the tine flanges 36 and the seal portion flanges 52 pressing from opposite sides on the outer wall surface



of the target vessel T and the everted portion of the graft vessel. Similarly, the seal portion 26 may be provided with distally-extending sharp end portions 90 in addition to, or in place of, the flanges 52.

5           It is also possible to use connector assembly 20 to attach the end of a graft vessel to the end of a target vessel. See Figs. 16-18. In this respect it should be appreciated that because the tines are between the sealing flanges, the flanges can press the  
10           two vessel layers down against the tines more securely. Connector assembly 20 can also be used for angled approaches as well as the end-to-side and end-to-end connections described above.

          Connector assembly 20 can be formed out of any  
15           biocompatible materials having characteristics consistent with the present invention. By way of example but not limitation, connector assembly 20 can be formed out of metals (including shape memory alloys) plastics, bioabsorbable materials, etc.

20           Connector assembly 20 can be used to connect various types of vessels including, but not limited to, blood vessels, intestine, or other tubular structures.

There is thus provided an improved apparatus and method for connecting a graft vessel to a target vessel without the need for the usual suturing or stapling procedures.

5           It is to be understood that the present invention is by no means limited to the particular construction and method steps herein disclosed and/or shown in the drawings, but also comprises any modification or equivalent within the scope of the disclosure. For  
10           example, in manufacture of the connector assembly, the spreader portion 24 and the seal portion 26 may be formed as a single integral unit or connected together, as by spot welds 92 connecting the flanges 46,56 (Fig. 3).

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